REMARKS

This amendment is submitted in response to the non-final Office action mailed November 14, 2007, in connection with the above-identified application (hereinafter, the "Office Action"). The Office Action provided a three-month shortened statutory period in which to respond, ending on February 14, 2008. Accordingly, this amendment is timely submitted.

I. Pending Claims

Claims 1-5, 7-11 and 13-17, of which claims 1, 2, 3 and 17 are independent, remain pending. New claims 23-29 are added. Claims 6, 12, and 18-22 are withdrawn. Applicant reserves the right to pursue the withdrawn claims in a divisional or continuation application, if not rejoined upon allowance of the pending claims. Applicant does not acquiesce in the correctness of the rejections or objections and reserve the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

The title has been amended to clearly describe the presently claimed invention. The specification has been revised to correct a typographical error that was pointed out by the Examiner. The error occurred during the publication of the patent application, US 2004/0087490 A1; however, the originally-filed application does not contain the error.

By this amendment, Applicant has amended independent claims 1, 2, 3, and 17 to include a Markush recitation of the essential amino acids (for claims 1, 2, 3, and 17) and conditionally essential amino acids (for claims 3 and 17) and to incorporate the phrase " and wherein the ratio of the intact protein to leucine in free form and/or salt form ranges from about 10:1 to about 1:10" (for claim 3). In addition, the phrase "at least one" has been inserted before the terms "essential," "conditionally" and "intact protein" (first occurrence) in claims 13 and 17.

With respect to independent claims 1 and 2, the claim has been further amended by changing the range of leucine content to (a) from 25% to about 95% by weight (for claim 1) and (b) from 25% to about 35% by weight (for claim 2).

In claim 4, the phrase "amino acid" has been inserted after the term "essential" and the phrase "and, optionally, conditionally..." has been deleted.

In claim 7 and withdrawn claim 6, a comma is added after the phrase "claim 3."

New claims 23-26 are added to further illustrate the embodiments of the presently claimed invention. More particularly, new independent claims 23, 24, 25 and 28, correspond to amended composition claims 1-3 and kit claim 17, respectively, but employ the transitional phrase "consisting essentially of." New dependent claim 26 is drawn to the composition of claim 3 that comprises from about 10 g to about 20 g of leucine in free and/or salt form per daily dose. New dependent claim 27 is also drawn to the composition of claim 3, which further comprises methionine in free and/or salt form in an amount of at least 5% to about 7% by weight based on the weight of the total amino acids.

New dependent claim 29 is drawn to the kit of claim 17, wherein the anticancer drug is 5-fluorouracil, mitomycin-C, adriamycin, chloroethyl nitrosureas or methotrexate. Support for this amendment is found on page 14, line 32-page 15, line 2 of the specification.

Support for the above amendments are found in the entire specification, particularly at pages 3-5; page 5, lines 20, 25-26, 32; page 6, lines 14-16; and page 10, line 30.

No new matter has been introduced in these amendments and in the addition of the new claims. Applicant submits that the rejections based on indefiniteness, lack of written description, anticipation and obviousness are overcome in view of the amendments and arguments presented in the response. Applicant therefore requests that all amendments be entered at this time and reconsideration of this application in view of the above amendments and the following remarks be made.

II. Objection and Minor Informalities

The title of the application now reads as "Methods and Compositions for Promoting Muscle Protein Synthesis."

In addition, the error identified at paragraph [0091], line 6 of the published application has been corrected, as pointed out by the examiner.

In view of the amendments, Applicant respectfully request the Examiner to withdraw his objections to the title and specification.

III. Rejection Under 35 U.S.C. § 112, Second Paragraph

On pages 4-5 of the Office Action, the Examiner rejected claims 3-5 under 35 U.S.C. §112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention." In particular, the phrases, "in an amount of about 55% to about 75% by weight based on the weight of the total amino acids" and "conditionally essential amino acid," as recited in these claims, are allegedly unclear.

Applicant respectfully traverses the rejections in view of the reasons provided hereinbelow.

As defined in the specification, the phrase "total amino acids" refers to "amino acid in free and/or salt form plus amino acid derived from or bound in, intact protein" (emphasis added). Examples of total amino acids include essential, conditionally essential or non-essential amino acids. See Specification, at page 4, lines 1-3. Accordingly, this phrase is clear and is defined accordingly in the Specification.

To address the purported lack of clarity of the rejected claims, Applicant has amended claim 3 by adding a Markush listing of amino acids that are described in the specification as conditionally essential amino acids. These amino acids include "tyrosine, cysteine, arginine and glutamine." See Specification, at page 3, line 20. In addition, the Specification does not need to provide a specific definition of this phrase because it is generally known and readily available in the art. One of the ordinary skill in the art would know where to go to look up for the meaning this phrase.

For example, as defined in the Wikipedia web dictionary, the "amino acids arginine, cysteine, glycine, glutamine and tyrosine are considered conditionally essential, meaning they are not normally required in the diet, but must be supplied exogenously to specific populations that do not synthesize it in adequate amounts." See http://en.wikipedia.org/wiki/Essential_amino_acid. In addition, conditionally essential amino acids are considered as such when some non-essential amino acids in adults are essential in infants, and others become essential when there are conditions in the body that prevent the biochemical conversion of one amino acid into another. See http://www.cocoonnutrition.org/catalog/page_aminoacids.php. Furthermore, in a Life Extension article entitled "Glutamine, the Conditionally Essential Amino Acids," published August 2003,

the author, Angela Pirisi wrote that "most scientists now consider glutamine to be a "conditionally" essential amino acid, because under certain conditions we are unable to make adequate amounts and thus need to obtain it from outside sources." As shown, the definition of the phrase "conditionally essential amino acid," is readily known, understandable and available for any person skilled in the art.

In light of the amendments and remarks presented hereinabove, Applicant respectfully submits that claims 3-5 are clear and no longer indefinite. Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of these claims based on 35 U.S.C. §112, second paragraph.

IV. Rejection Under 35 U.S.C. § 112, First Paragraph

On pages 5-11 of the Office Action, the Examiner rejected claims 3-5, 7-11 and 13-17 under 35 U.S.C. §112, first paragraph, "as failing to comply with written description." In particular, the "generic statements intact protein and anti-cancer drug do not provide ample written description for the compounds since the claims do not describe a single structural feature."

Applicant respectfully traverses the rejections.

To better clarify the claimed invention and address the Examiner's concerns, Applicant has amended independent claims 3 and 17 by adding a Markush listing of members of the intact protein, i.e., casein, whey protein, soy protein, collagen and wheat protein. In addition, Applicant has added new dependent claim 27, drawn to the kit of claim 17, wherein the anticancer drug is 5-fluorouracil, mitomycin-C, adriamycin, chloroethyl nitrosureas or methotrexate.

Based on the foregoing and claim amendments, Applicant respectfully submits that the Specification meets the written description requirement for the claimed invention. Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of claims 3-5, 7-11 and 13-17 based on 35 U.S.C. §112, first paragraph.

V. Rejection Under 35 U.S.C §102

At pages 11-12 of the Office Action, the Examiner rejected claims 1-2 under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 4,498,879 to Madsen et al. (referred hereinafter

as "Madsen"). According to the Examiner, Madsen anticipates claims 1 and 2 based on its disclosure of a nutritional composition that "comprises about 19.4 to 19.8% of leucine and about 1.1 to 1.2% methionine." In addition, Madsen allegedly "teaches that essential amino acids should comprise about from 60-75% by weight of the total amino acids." Applicant respectfully traverses this rejection for the reasons set forth hereinbelow.

At the outset, amended claim 1, as recited, is drawn to a composition that comprises leucine and at least one essential amino acid in free and/or salt form, wherein the leucine in free and/or salt form, is present in an amount of at least about 25% to about 95% by weight based on the weight of the total amino acids. And in amended claim 2, the range of leucine in the composition has been amended to recite as from about 25% to about 35% by weight based on the weight of the total amino acids. Madsen, however, fails to describe a composition that wherein the range of leucine is at least about 25% to about 95% or from about 25% to about 35% by weight based on the weight of the total amino acids. In fact, Madsen's leucine level is lower than that of the claimed compositions.

In addition, Applicant has added new independent claims 23 and 24 that correspond to the original claims 1 and 2 except that the new claims use a transitional language, "consisting essentially of" instead of "comprising." Applicant would like to stress that Madsen's nutritional composition for management of hepatic failure includes a cysteine-free mixture of essential and non-essential amino acids, such as tyrosine, arginine, proline, alanine, and glycine (with histidine as semi-essential). Contrary to Madsen, the presently-claimed composition, as set forth in new claims 28 and 29, as well as in amended claims 1 and 2, do not encompass any non-essential amino acids.

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

In view of the claim amendments and remarks presented hereinabove, Applicant respectfully submits that Madsen fails to anticipate the subject matter, as set forth in amended claims 1 and 2, as well as new independent claims 23 and 24, and fails to render the claimed invention obvious. Because Madsen fails to describe and suggest each and every element of the claimed composition, it is, thus, not an anticipating-defeating reference. Thus, Applicant

respectfully requests that the Examiner reconsiders and withdraws the lack of novelty rejection of claims 1-2 based on Madsen.

At pages 12-13 of the Office Action, the Examiner rejected claims 3-5 and 7 under 35 U.S.C. §102(e) and §102(a), as being anticipated by U.S. Patent No. 6,420,342 to Hageman et al. (referred hereinafter as "Hageman"). Applicant respectfully traverses the rejection.

Hageman describes a nutritional preparation for supporting total nucleotide metabolism that includes the following necessary active components: ribose or its functional equivalents and folic acid. In one of the examples provided, as cited in the Office Action, the nutritional composition may be mixed with a mixture of amino acids that appeared to be especially beneficial for muscle growth when consumed in an amount more than 2...per daily dose: 3-10 wt % histidine, 5-15 wt % isoleucine, 10-23 wt % leucine, 10-23 wt % lysine, 5-15 wt % methionine, 5-15 wt % phenylalanine, 5-15 wt % threonine. See Hageman, at column 6, line 62-column 7, line 1. However, this product, if prepared in this manner, should contain no or little protein. See Hageman, at column 7, lines 1-2.

Contrary to Hageman, amended claim 3 is drawn to a composition that comprises (a) at least one essential amino acid in free form and/or salt form selected from the group consisting of isoleucine... and, optionally, at least one conditionally essential amino acid selected from the group consisting of tyrosine... in free form and/or salt form, and (b) at least one intact protein selected from the group consisting of casein..., wherein the total essential amino acids and, optionally, conditionally essential amino acids are present in an amount of about 55% to about 75% by weight based on the weight of total amino acids and wherein the ratio of the intact protein to leucine in free form and/or salt form ranges from about 10:1 to about 1:10. The claimed composition, therefore, requires that it contains not only a certain percentage of essential amino acids and, optionally, conditionally essential amino acids and intact proteins, but also requires a particular ratio range of intact protein:leucine. As mentioned earlier, Hageman's sportsmen's composition should contain no or little protein. This is definitely not the same for the claimed composition and is not set forth in amended claim 3 and dependent claims 4-5.

In addition, claim 7 is drawn to the composition according to amended claim 3, wherein the range of methionine in free and/or salt forms ranges from at least about 0.5% to about 5% by weight based on the weight of the total amino acids. In Hageman, the level of methionine is

from 5-15 wt %, which falls under a higher range than what is encompassed in dependent claim 7.

In view of the claim amendments and remarks presented hereinabove, Applicant respectfully submits that Hageman fails to anticipate the subject matter as set forth in amended claims 3-5 and 7, as well as new independent claim 25, and fails to render the claimed invention obvious. Because Hageman fails to describe and suggest each and every element of the claimed composition, it is, therefore, not an anticipating-defeating reference. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw the lack of novelty rejection of claims 3-5 and 7, in view of Hageman.

At pages 13-15 of the Office Action, the Examiner rejected claims 3-4, 7-11 and 15 under 35 U.S.C. §102(e) and §102(a), as being anticipated by U.S. Patent No. 6,387,883 to Abbruzzese et al. (referred hereinafter as "Abbruzzese"). Applicant respectfully traverses the rejection.

Abbruzzese describes and suggests methods and nutritional compositions for preventing and treating cachexia and anorexia. Abbruzzese's composition includes effective amounts of (1) ω-3 fatty acids, such as α-linolenic acid, stearidonic acid, eicosapentaenoic acid, docosapentaenoic acid, docosahexaenoic acid or mixtures thereof; (2) branched-chain amino acids, such as valine, leucine, isoleucine or mixtures thereof; with or without reduced levels of tryptophan and 5-hydroxytryptophan; and (3) an anti-oxidant system selected from the group consisting of beta-carotene, vitamin C, vitamin E, selenium, or mixtures thereof. See Abbruzzese's abstract.

The total amount of branched-chain amino acids (BCAAs) according to Abbruzzese is about 15-50 g/100g protein (i.e. percent). For example, in an eight-ounce container of the nutritional composition, there is about 8 g of BCAAs per 16 grams of total protein, which is 50% of BCAAs by weight based on the weight of total protein. The daily delivery of BCAAs is about 5-26 g. In Table 4 of Abbruzzese, the amounts of leucine and methionine are 9.08 g (%) and 2.78 g (%), respectively. Abbruzzese at column 9, lines 26-31 and Table 4. The amounts of intact proteins, e.g., whey protein, sodium caseinate, and soy lecithin, as described in Table 7, are 184.46 kg, 1427.04 kg, 42.64 kg, respectively. See Abbruzzese at column 11, Example I, Table 7. In Example II, Abbruzzese added two test compositions, designed as "high" and "low," that contain two different concentrations of the three BCAAs and mixed them with the

nutritional composition as described in Table 7 of Example I. The concentration of leucine used in the "high test" was 2.5 g/237 mL serving and in the "low test", the leucine was at 1.3 g/237 mL. Abbruzzese at column 14, Table 10, lines 41-66.

Contrary to Abbruzzese, the claimed composition, as set forth in amended claim3, is drawn to a composition that comprises (a) at least one essential amino acid in free form and/or salt form selected from the group consisting of isoleucine... and, optionally, at least one conditionally essential amino acid selected from the group consisting of tyrosine... in free form and/or salt form, and (b) at least one intact protein selected from the group consisting of casein..., wherein the total essential amino acids and, optionally, conditionally essential amino acids are present in an amount of about 55% to about 75% by weight based on the weight of total amino acids and wherein the ratio of the intact protein to leucine in free form and/or salt form ranges from about 10:1 to about 1:10.

Applicant respectfully submits that the presently-claimed compositions, as set forth in amended claim 3, as well as the claims that depend therefrom, are distinct from that of Abbruzzese for the following reasons: (1) the amount of total amino acids of the present invention is higher than that of Abbruzzese, i.e., from about 55% to about 75% by weight based on the weight of total amino acids versus Abbruzzese's 50% of BCAAs by weight based on the weight of total protein; and (2) the ratio of the intact protein to leucine in free form and/or salt form is completely different from that of Abbruzzese. The claimed invention has a range from about 10:1 to about 1:10 whereas, in Abbruzzese, the level of intact protein is definitely over 1,000 fold higher than the level of leucine.

In view of the amendments and remarks presented hereinabove, Applicant respectfully submits that Abbruzzese, similar to Hageman, fails to describe and teach each and every element of amended claim 3 and the claims that depend therefrom and fails to render the claimed invention obvious. It also fails to anticipate new independent claim 25 and new dependent claims 26-27. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the Examiner's rejection of claims 3-4, 7-11 and 15 based on 35 U.S.C. §§102(a) and (e).

VI. Rejection Under 35 U.S.C §103

At pages 15-18 of the Office Action, the Examiner rejected claims 3-4, 7-11, 14 and 15-16 under 35 U.S.C §103(a) as being unpatentable for obviousness over Abbruzzese.

Applicant respectfully traverses this rejection.

The various deficiencies of Abbruzzese as a reference have been enumerated above. The above arguments applied to rebut the Examiner's anticipation rejection based on Abbruzzese are incorporated herein to demonstrate further deficiencies of Abbruzzese as a cited reference.

Applicant respectfully submits Abbruzzese fails to describe or suggest the claimed compositions that that comprise (a) at least one essential amino acid in free form and/or salt form selected from the group consisting of isoleucine... and, optionally, at least one conditionally essential amino acid selected from the group consisting of tyrosine... in free form and/or salt form, and (b) at least one intact protein selected from the group consisting of casein..., wherein the total essential amino acids and, optionally, conditionally essential amino acids are present in an amount of about 55% to about 75% by weight based on the weight of total amino acids and wherein the ratio of the intact protein to leucine in free form and/or salt form ranges from about 10:1 to about 1:10. "Where the prior art gives no indication which parameters are critical and no direction as to which many possible choices is likely to be successful, the fact that the claimed combination falls within the scope of possible combinations taught therein does not render it unpatentably obvious." *In re O'Farrell*, 7 U.S.P.Q. 2d 1673 (CAFC 1988). Applicant respectfully submits that one of ordinary skill in the art, upon reading the Abbruzzese reference, would not have the knowledge nor motivation to practice the presently-claimed invention. Nor would there be any expectation of success to practice or use the claimed invention. The total lack of direction toward the subject matter of the present invention, as currently claimed, renders the Abbruzzese reference inapplicable to an obviousness rejection.

In view of the foregoing remarks and claim amendments, Applicant respectfully submits that Abbruzzese, like the Madsen and Hageman references, fails to describe or suggest the subject matter of claims 3-4, 7-11, 14 and 15-16, as well as new claims 23-25. *See* MPEP 2143.03. ("To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art").

Applicant respectfully submits that the present invention, as claimed herein, is neither anticipated by nor rendered obvious in view of the Abbruzzese reference.

Reconsideration and withdrawal of the §§ 112, first and second paragraphs, 102(a) and (e) and 103(a) rejections of claims 1-5, 7-11 and 13-17, as well as of new claims 23-29, are respectfully requested.

CONCLUSION

For at least the reasons set forth above, this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly requested. Should the Examiner have any questions that would facilitate further prosecution or allowance of this application, the Examiner is invited to contact the Applicant's representative designated below.

Respectfully submitted,

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